

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

Remarks

Claims 1, 5-27, 51-55, and 61-63 are pending in this application. Claims 2-4, 28-50, and 56-60 have been cancelled without prejudice or disclaimer.

Claims 1, 51 and 61 have been amended to replace the term a "bacterial disorder" with the term "impetigo." Support for claims 1, 51 and 61 as amended appears in the present specification in paragraphs 19, 69, and 122 and in claims 2 and 58 as originally filed. No new matter has been added.

Claim 21 has been amended to correct a minor typographical error. No new matter has been added.

Applicant, by canceling or amending any claims, makes no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicant reserves the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Submitted herewith is a complete copy of the Baltimore reference applied by the Examiner under 35 USC § 103 against claim 58 directed to the treatment of impetigo, i.e., Baltimore, Robert S., *Treatment of Impetigo: a review*, *Pediatric Infectious Disease*, Vol. 4, No. 5, pp. 597-601 (1995).

In view of the following, further and favorable consideration is respectfully requested.

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

I. ***At page 2 of the Official Action, claims 1-63 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of co-pending application no. 10/617,191 and over claims 1-57 of co-pending application no. 10/791,862 in view of US 6,150,381.***

The Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from each other. The Examiner notes that the instant claims are directed to a method of treating a bacterial skin disorder or infection or the conditions associated with bacterial infections using a composition comprising benzoyl peroxide and clindamycin. The Examiner asserts that the claims of the co-pending '191 application also recite that the presently employed composition is used for bacterial skin conditions and that the claims of the co-pending '862 application recite a method of treating rosacea with the same composition.

Claims 2-4, 28-50, and 56-60 have been cancelled without prejudice or disclaimer, rendering this rejection moot as to these claims. In view of the following, this rejection is respectfully traversed.

Present claims 1, 5-27, 51-55, and 61-63 are directed to methods of treating impetigo.

It is submitted that present claims 1, 5-27, 51-55, and 61-63 are patentably distinct from the claims pending in co-pending application no. 10/617,191 and the claims pending in co-pending application no. 10/791,862.

Claims 1-25 and 32-37 of co-pending application no. 10/617,191 were canceled in an Amendment filed on October 31, 2007 with the United States Patent and Trademark Office. Remaining claims 26-31 are directed to a process

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

for preparing a storage-stable topical composition for treating a skin disorder or condition. None of co-pending claims 26-31 are directed to a method of treating impetigo as presently claimed. Accordingly, present claims 1, 5-27, 51-55, and 61-63 are patentably distinct from claims 26-31 of co-pending application no. 10/617,191.

With regard to claims 1-57 of co-pending application no. 10/791,862, all of claims 1-57 are *method claims* directed to a method of treating rosacea. Again, present claims 1, 5-27, 51-55, and 61-63 are method claims directed to a method of treating impetigo. Impetigo is a disorder that is distinct from rosacea. Unlike Impetigo, Rosacea is a disorder that can be caused by mite organisms. Present claims 1, 5-27, 51-55, and 61-63 are directed to treating a *different patient population* than are claims 1-57 of co-pending application no. 10/791,862. Accordingly, present claims 1, 5-27, 51-55, and 61-63 are patentably distinct from claims 1-57 of co-pending application no. 10/791,862.

In view of the foregoing, it is submitted that present claims 1, 5-27, 51-55, and 61-63 are patentably distinct from claims 26-31 of co-pending application no. 10/617,191 and from claims 1-57 of co-pending application no. 10/791,862. Accordingly, the Examiner is respectfully requested to withdraw this rejection of pending claims 1, 5-27, 51-55, and 61-63.

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

II. At page 4 of the Official Action, claims 1-4, 10-16, 28, 29, 40-43, 46-57, and 61-63 have been rejected under 35 USC § 102(b) as being anticipated by US Patent No. 6,117,843 to Baroody et al.

The Examiner asserts that Baroody et al. meets the limitations of the rejected claims. The Examiner further states, at page 7 of the Official Action, that Baroody et al. "fails to teach impetigo."

Claims 2-4, 28, 29, 40-43, 46-50, and 56-57 have been cancelled without prejudice or disclaimer, rendering this rejection moot as to these claims. In view of the following, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Present claims 1, 5-27, 51-55, and 61-63 are directed to methods of treating impetigo.

Baroody et al. does not teach or suggest a method of treating impetigo. Rather, Baroody et al. describes only methods of treating acne.

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

In view of the foregoing remarks, it is submitted that Baroody et al. does not teach each and every element of present claims 1, 5-27, 51-55, and 61-63 as required for anticipation under 35 USC § 102(b). Accordingly, the Examiner is respectfully requested to withdraw this rejection of pending claims 1, 10-16, 51-55, and 61-63.

III. *At page 5 of the Official Action, claims 1-4, 10-16, 28, 29, 40-43, 46-57, and 61-63 have been rejected under 35 USC § 103(a) as being unpatentable over US Patent No. 6,117,843 to Baroody et al. in view of US Patent No. 6,150,381 to Subbiah and Rosen et al.*

The Examiner asserts that it would have been obvious for the skilled artisan "to use the composition of Baroody et al. for treating several bacterial skin disorders caused by acne bacterium, i.e., folliculitis, rosacea, etc., because '381 suggests benzoyl peroxide as effective for the bacterial skin disorders...and Rosen teaches clindamycin is effective for treating acne as well as the conditions such as folliculitis etc. Thus, a skilled artisan would have expected to inhibit not only acne causing bacterial but also the skin conditions associated with the infection, with the composition of Baroody.

The Examiner states, at page 5 of the Official Action, that Baroody et al. does not teach the purity of benzoyl peroxide, viscosity of benzoyl peroxide of claim 13, the percentage degradation of clindamycin or the amounts of benzoyl peroxide and clindamycin in the claimed standard deviation. The Examiner further states, at page 7 of the Official Action, that Baroody et al. "fails to teach impetigo."

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

Claims 2-4, 28, 29, 40-43, 46-50, and 56-57 have been cancelled without prejudice or disclaimer, rendering this rejection moot as to these claims. In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S. ____ (April 30, 2007), “a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” (*KSR, supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991).

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Regarding *teaching away*, **MPEP 2141.02** states that prior art must be considered in its entirety, including disclosures that *teach away* from the claims. See also **MPEP 2145(X)(D)**. The Federal Circuit in *Takeda v. Alphapharm* found that the prior art taught away from the closest compound because the prior art in fact disclosed a broad selection of compounds where the closest prior art compound exhibited negative properties that would have led the skilled artisan away from that compound.

In *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, Federal Circuit, No. 06-1325 (June 28, 2007), the Federal Circuit rejected Alphapharm's argument that the prior art would have led one of ordinary skill in the art to select compound b as a lead compound most promising to modify in order to improve its antidiabetic activity and thus potentially arrive at the claimed pioglitazone. The district court considered three references in reaching its determination, namely Takeda's '200 patent; Sodha II; and Takeda's '779 patent. The district court found that Sodha II taught away from compound b and that any suggestion in the '779 patent to select compound b was essentially negated by the disclosure of Sodha II in view of the more exhaustive and reliable scientific analysis presented by Sodha II and the teaching away. Accordingly, the Federal Circuit accorded more weight to the Sodha II reference.

It is submitted that a *prima facie* case of obviousness has not been established because the Baroody et al., Subbiah, and Rosen et al. references fail

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

to teach or suggest all of the limitations of the claims as required by *In re Wilson*.

All of the present claims 1, 5-27, 51-55, and 61-63 are directed to methods of treating impetigo. As admitted by the Examiner on page 7 of the Official Action, Baroody et al. "fails to teach impetigo." The Examiner also states, at page 6 of the Official Action, that "Baroody teaches that the composition is effective for acne but does not specifically state the bacterial conditions such as folliculitis, erythrasma etc." Applicants submit that neither Subbiah nor Rosen et al. cure the deficiencies of Baroody et al.

Subbiah is directed to methods of treating skin conditions including acne vulgaris and folliculitis with an effective amount of an active compound that is a sclareol-like or a sclareolide-like compound. Subbiah does not teach or suggest treating impetigo. Accordingly, Subbiah does not cure the deficiencies of Baroody et al.

Rosen et al. describes the topical treatment of acne vulgaris, erythrasma, rosacea, dermatitis and folliculitis with oral and topical clindamycin. Rosen et al. does not teach or suggest treating impetigo. Accordingly, Rosen et al. does not cure the deficiencies of Baroody et al. and Subbiah.

In addition, with regard to claims 5-9 and 52-54, the Examiner asserts, on page 5 of the Official Action, that "Baroody does not teach...viscosity of benzoyl peroxide of claim 13,...However, Baroody also recognize the same factors i.e., pH, viscosity etc., that affect the stability...therefore it would have been obvious...to employ pure active compounds and optimize the general conditions

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

such as viscosity,...." Applicants submit that Baroody et al. does not teach or suggest the presently claimed viscosities.

Claim 5 is directed to the method of claim 1, wherein the topical composition has a viscosity lower than the viscosity of the benzoyl peroxide dispersion before mixing. Claims 6-9 are directly or indirectly dependent on claim 5. See also present claims 52-54.

Baroody et al. describes, at col. 4, lines 48-52 that "the gelling agent ideally will be selected to have a reduced viscosity at the pH of the first component and an increased viscosity at the stage of the final product obtained when the two components are combined." Baroody et al. further states, at col. 5, paragraph 2, the following:

The benzoyl peroxide component...itself may be maintained at a relatively low viscosity while the final topical composition...with have a relatively higher viscosity. In this way, mixing of the two components to form the topical composition is facilitated (i.e. the lower viscosity of the benzoyl peroxide component makes the combination and mixing with the clindamycin component easier) while the final topical composition can still possess the desired higher viscosity, gel consistency.

See also, col. 3, lines 29-36 and col. 6, lines 5-6 and 48-58. In complete contrast to the method of present claims 5-9 and 52-54, Baroody et al. teaches that to facilitate mixing, the viscosity of the benzoyl peroxide dispersion before mixing is *lower* than the viscosity of the final composition. Again, present claims 5-9 and 52-54 recite that the ***topical composition has a viscosity lower*** than the viscosity of the benzoyl peroxide dispersion before mixing. Accordingly, Baroody et al. does not teach or suggest the methods of present claims 5-9 and 52-54 within the meaning of 35 USC § 103(a).

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

In view of the foregoing, it is submitted that nothing in any of Baroody et al., Subbiah, and Rosen et al., teach or suggest the presently claimed subject matter within the meaning of 35 USC § 103(a). Thus, the Examiner is respectfully requested to withdraw this rejection of present claims 1, 5-27, 51-55, and 61-63.

IV. *At page 5 of the Official Action, claim 58 has been rejected under 35 USC § 103(a) as being unpatentable over US Patent No. 6,117,843 to Baroody et al. in view of Baltimore.*

The Examiner asserts that it would have been obvious for the skilled artisan to have “employed the composition of Baroody in the treatment of impetigo” because Baltimore teaches clindamycin treatment for impetigo. At page 7 of the Official Action, the Examiner states that Baroody et al. “fails to teach impetigo.”

Claim 58 has been canceled without prejudice or disclaimer, rendering this rejection moot with regard to this claim. In view of the following, this rejection is respectfully traversed.

All of the pending claims are directed to methods of topically treating impetigo. A discussion of the relevant authority is set forth above and is incorporated herein by reference in its entirety. Please see the above discussion.

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

It is submitted that a *prima facie* case of obviousness has not been established because the Baroody et al. and Baltimore references fail to teach or suggest all of the limitations of the claims as required by *In re Wilson*. Further, Applicant submits that the Baltimore reference **teaches away** from the presently claimed subject matter.

Again, as admitted by the Examiner, Baroody et al. fails to teach the topical treatment of impetigo. It is submitted that Baltimore does not cure the deficiencies of Baroody et al.

Contrary to the Examiners assertion, Baltimore does not teach that topically applied clindamycin is effective against impetigo. Rather, Baltimore describes that oral or injectable antibiotics are far superior and that clindamycin has been shown to be extremely effective as such. More specifically, Baltimore states the following: "A number...oral or injectable antibiotics over typical treatment in the treatment of impetigo...Erythromycin...as well as clindamycin,...have been shown to be extremely effective." Further, Baltimore states that intramuscular benzathine penicillin G has consistently been associated with the highest cure rates, especially in studies specifically of streptococcal impetigo.

Nowhere does Baltimore teach or suggest that clindamycin is topically effective against impetigo. In fact, Baltimore discusses at length the superiority of oral or injectable antibiotics, particularly, penicillin, for the treatment of impetigo.

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

In fact, Baltimore **teaches away** from the topical treatment of impetigo. That is, the skilled artisan, in view of Baltimore, would be led away from the topical treatment of impetigo with any antibiotic, let alone clindamycin.

Baltimore describes, in Table 2 on page 598, a large number of studies that compared the efficacy of systemic antibiotic treatment of impetigo to topical treatment. Table 2 of Baltimore is discussed at pages 597-600. Baltimore summarizes, at page 599, that "...systemic antibiotics have always been superior to topically applied antibiotics whether one measures the outcome by morphology of the lesions or by inability to recover the infecting organisms, and whether the interval of observation ranges anywhere from 5 to 14 days." Further, nowhere does Baltimore provide data as to clindamycin treatment, either systemically or topically.

Clearly, the skilled artisan in view of Baltimore would have no motivation to topically treat impetigo, let alone topically treat impetigo with clindamycin, in view of Baltimore's conclusion that systemic antibiotic treatment is superior to topically applied antibiotics. Accordingly, Baltimore **teaches away** from the topical treatment of impetigo.

In view of the foregoing, it is submitted that nothing in Baroody et al. and Baltimore, taken alone or together, teach or suggest the presently claimed subject matter within the meaning of 35 USC § 103(a). Thus, the Examiner is respectfully requested to withdraw this rejection.

MAIL STOP AMENDMENT
Attorney Docket No. 24948X2

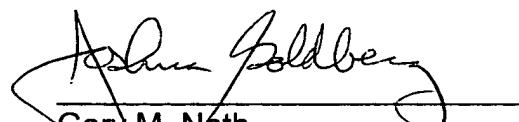
CONCLUSION

In view of the foregoing, Applicant submits that the application is in condition for examination on the merits. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



Gary M. Nath
Registration No. 26,965
Joshua B. Goldberg
Registration No. 44,126
Susanne M. Hopkins
Registration No. 33,247
Customer No. 20259

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THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
Tel: (703) 548-NATH
Fax: (703) 683-8396